# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## A review of tension headaches in Iranian medicine and comparison the effects of the of Valerian extraction and placebo on severity and duration of headaches in patients with tension-type headache

## Protocol summary

**Study aim**

Determination of Valeriana Officinalis effect on severity of Tension headache (TH) in comparison with placebo; determination of Valeriana Officinalis effect on duration of Tension headache (TH) in comparison with placebo; determination of Valeriana Officinalis effect on frequency of Tension headache (TH) in comparison with placebo; determination of Valeriana Officinalis effect on disability of Tension headache (TH) in comparison with placebo

**Design**

Parallel double blind randomised clinical trial with repeated measurement of outcome

**Settings and conduct**

This double blind randomized clinical trial will be conducted at the Neurological Clinic of the Aria Hospital of Mashhad for one year. All patients aged 18 to 65 suffering headaches and diagnosed by a neurologist based on the ICHD-III criteria, and are under treatment with common medicines and having medical registry can be included in the RCT. After sample size calculation, 110 eligible patients will be recruited and will be assigned randomly to intervention and placebo group. This is a double blind RCT which GP and patients are blinded.

**Participants/Inclusion and exclusion criteria**

Eligibility criteria Agreement for participation; Filling the informed consent form; Age between 18 and 65 years; Suffering from tension headache based on ICHD-III criteria; Exclusion criteria Suffering uncommon headache or probable headache or other primary and secondary headache; feeling headache with moving the head; history of metabolic disorder or skeleton disorder which cause similar headache; history of trauma; sign of dizziness with unknown cause; stiffness of the joints, atherosclerosis or advanced arthritis; emotional stress; neurological disorder; taking barbiturates or sedative medications; history of Valeriana Officinalis intake or its products in the past month; pregnancy and lactation; diabetes; hypertension; heart disease; liver and kidney disease, and chronic psychological illness; history of hypotension (with or without medication); history of taking anti-coagulation medications, antiplatelet, heparin, thrombotic agents, opioid analgesics and loperamide.

**Intervention groups**

The Valeriana Officinalis and placebo capsules, each in cans containing 60 capsules, will be delivered to a specialist for assignment to intervention and control groups; for duration of one month (two capsule per day after dinner). Label B assigned to Valeriana Officinalis cans and A label assigned to placebo cans.

**Main outcome variables**

Severity of the headache; duration of headache; frequency of headache; side effects; headache severity; disability

## General information

**Reason for update**

**Acronym**

THV

**IRCT registration information**

IRCT registration number: **IRCT20171203037738N1**
Registration date: **2018-03-16, 1396/12/25**
Registration timing: **prospective**

Last update: **2018-03-16, 1396/12/25**
Update count: **0**

**Registration date**

2018-03-16, 1396/12/25

**Registrant information**

**Name**

Hosein Azizi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**
+98 51 5224 0095
**Email address**
azizi.h@tak.iums.ac.ir

**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2018-04-21, 1397/02/01
**Expected recruitment end date**
2018-07-23, 1397/05/01
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
A review of tension headaches in Iranian medicine and comparison the effects of the of Valerian extraction and placebo on severity and duration of headaches in patients with tension-type headache

**Public title**
Effect of Valerian on tension headache
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Complete written informed consent Age between 18 to 65 years Suffering from common or chronic tension headache based on the International Association Headache (ICHD-III) criteria Be under treatment with medications Not completed treatment (for headache) Informed consent
**Exclusion criteria:**
Patients with uncommon or probable headache or other primary or secondary headaches Headache increases with head movement Metabolic or musculoskeletal disorders that cause similar headache symptoms History of trauma to the spinal cord True or false vertigo Rigidity of the joints, atherosclerosis or advanced arthritis Emotional stress Neurological disorders Taking barbiturates or sedative medications (classic or traditional medicine) The consumption of valerian or its products in the past month Pregnancy and lactation Having underlying disease including diabetes, hypertension, heart disease, liver and kidney disease, and chronic psychological disease History of hypotension (with or without medication) Use of anticoagulants, antiplatelet, heparin, thrombotic agents, opioid analgesics and loperamide Patient headaches improve with taking triptans
**Age**
From **18 years** old to **65 years** old
**Gender**
Both

**Phase**
N/A

**Groups that have been masked**

- Participant
- Care provider

**Sample size**
Target sample size: **110**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
We will use random digit for randomization. The unit of randomization is each patients. We will use Microsoft Excel for generation of random digits. Also, this is a double blind RCT and patients and practitioners are not aware about the interventions.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Patients and practitioners should be blind about the interventions.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Iran University of Medical Sciencs
**Street address**
Iran University of Medical Sciences, Hemat Highway, Tehran
**City**
Tehran
**Province**
Tehran
**Postal code**
1449614535
**Approval date**
2017-10-10, 1396/07/18
**Ethics committee reference number**
IR.IUMS.FMD.REC1396.9321309012

## Health conditions studied

### 1

**Description of health condition studied**
Tension Headache
**ICD-10 code**
G44.22
**ICD-10 code description**
Chronic tension-type headache

## Primary outcomes

### 1

**Description**
Frequency of headache and disability caused by headache are our main outcomes measures.
**Timepoint**
Per 4 weeks
**Method of measurement**
We will employ HDI and HIT-6 questionnaires.

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Valeriana capsule contain 530 mg Valeriana root powder.
**Category**
Treatment - Other

### 2

**Description**
Control group: placebo capsule contain 50 mg breadcrumbs powder.
**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Neurology Clinic of Aria Hospital in Mashhad
**Full name of responsible person**
Hosain Azizi
**Street address**
Aria Hospital, Golestan Street, Mashhad, Iran
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
4146749454
**Phone**
+98 51 3222 9094
**Email**
azizitarin@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Hosain Azizi
**Street address**
Iran university of medical sciences, Hemat highway
**City**
Tehran
**Province**
Tehran
**Postal code**
1449614535
**Phone**
+98 51 5224 5762
**Fax**
+98 51 5224 5762
**Email**
azizitarin@gmail.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
PhD thesis
**Proportion provided by this source**
100
**Public or private sector**
Public
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Hosain Azizi
**Position**
Consultant
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Traditional Medicine
**Street address**
Iran university of medical sciences, Hemat Highway
**City**
Tehran
**Province**
Tehran
**Postal code**
1449614535
**Phone**
+98 51 5224 5762
**Fax**
+98 51 5224 5762
**Email**

azizitarin@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Hosein Azizi
**Position**
PhD student
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Traditional Medicine
**Street address**
Iran university of medical sciences, Hemat highway
**City**
Tehran
**Province**
Tehran
**Postal code**
1449614535
**Phone**
+98 51 5224 5762
**Email**
azizitarin@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Hossein Azizi
**Position**
Consultant
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Traditional Medicine
**Street address**
Gharani Street, gharani 1 Ave, Torbat Heydarieh
University of Medical Sciences
**City**
Torbat Heydarieh
**Province**
Razavi Khorasan
**Postal code**
۹۵۱۶۹۱۵۱۶۹
**Phone**
+98 51 5222 8025
**Email**
azizitarin@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
No permission for sharing the IPD data
**Study Protocol**
No - There is not a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available
**Title and more details about the data/document**
Not making a decision for sharing the data
**When the data will become available and for how long**
Not making a decision for sharing the data
**To whom data/document is available**
Co-authors, corresponding author
**Under which criteria data/document could be used**
Not available for other researchers
**From where data/document is obtainable**
Not available for other researchers
**What processes are involved for a request to access data/document**
Not available for other researchers
**Comments**